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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/523,475	09/16/2005	Magdalene M. Moran	110313.139US2	2300
23483 7590 07/19/2007 WILMER CUTLER PICKERING HALE AND DORR LLP 60 STATE STREET BOSTON, MA 02109			EXAMINER HAMA, JOANNE	
			ART UNIT 1632	PAPER NUMBER
			NOTIFICATION DATE 07/19/2007	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/523,475	Applicant(s) MORAN ET AL.	
	Examiner Joanne Hama, Ph.D.	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 September 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-74 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-74 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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This application is a 371 of PCT/US03/24359, filed August 4, 2003, which claims priority to U.S. Provisional Application 60/402,115, filed August 7, 2002.

Amendment to the claims was filed February 4, 2005. Claims 75-111 are cancelled. Claims 12, 15, 16, 19-23, 36-38, 46, 54, 56, 58, 65, 67, 69, 73 are amended.

Claims 1-74 are pending

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1-25, 50-56, 58-67, 69-74, drawn to an isolated nucleic acid encoding CatSper4 protein, an isolated nucleic acid sequence encoding CatSper4 operably linked to a regulatory region, a kit for detecting at least a portion of a nucleic acid sequence encoding CatSper4, a vector comprising a nucleic acid sequence encoding CatSper4, a cell transformed with CatSper4, and a method of decreasing fertility comprising administering a compound which decreases CatSper4 activity.

Group 2, claim(s) 26-28, drawn to a transgenic animal comprising a genetic construct, wherein the construct modifies the genome of said animal, wherein the modification is an insertion of CatSper4, inactivation of endogenous CatSper4, and insertion by homologous recombination of a reporter gene operably linked to CatSper4 regulatory elements.

Group 3, claim(s) 29-32, drawn to a substantially pure protein preparation of CatSper4.

Group 4, claim(s) 33-40, 50-74, drawn to a substantially pure antibody preparation raised against CatSper4, and a kit comprising the antibody, and a method of decreasing fertility comprising administering a compound which decreases CatSper4 activity.

Group 5, claim(s) 41-55, 58-66, 69-72, 74, drawn to a method of identifying a potential modulator of CatSper4 activity, a method of decreasing fertility of a subject comprising

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administering a compound which decreases CatSper4 activity and to a contraceptive compound which decreases CatSper4 activity.

The inventions listed as Groups 1-5 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

unity of invention between different categories of inventions will only be found to exist if the specific combinations are present. These combinations include:

- 1) a product and special process of manufacture of said product,
- 2) a product and a process of use of said product,
- 3) a product, a special process of manufacture of said product, and a process of use of said product,
- 4) a process and an apparatus specially designed to carry out said process,
- 5) a product, a special process of manufacture of said product, and an apparatus specially designed to carry out said process.

The allowed combinations do not include multiple products, multiple methods of using said product, and methods of making multiple products as claimed in the instant application, see MPEP § 1850. In addition to this, Martelange et al., 2000, Cancer Research 60: 3848-3855 teach that 15 consecutive nucleic acid sequences of SEQ ID NO. 1 were known at the time of filing. A BLAST search of bases 121-135 of SEQ ID NO. 1 is the same as Homo sapiens sarcoma antigen 1 (SAGE 1), see BLAST search, pages 3 and 7. A copy of the Martelange et al., 2000, publication has been provided for the Applicant.

Groups 1-5 are distinct from each other. Groups 1-5 are drawn to distinctly named products: nucleic acid encoding CatSper4, transgenic animal comprising a nucleic acid encoding CatSper4 or a disruption of Catsper4 in its genome, a protein preparation of CatSper4, an antibody against CatSper4, and a compound that decreases CatSper4 activity and are thus separated from each other. The search and examination for each Group is burdensome because the searches are not coextensive.

The Groups are further restricted.

Group 1 is drawn to distinctly named nucleic acids, SEQ ID NO. 1 and SEQ ID NO. 3, and one must be elected. Each of the sequences is distinct from each other because each comprises a distinct sequence and each has a distinct activity. The search and examination of each SEQ ID NO. are burdensome because the searches are not coextensive.

Group 1 is drawn to distinctly named sequences which are sense and antisense (e.g. see claims 1(f) and 2(f)) and one must be elected. Sense and antisense sequences are distinct from each other because each has a different structure and different biological activity. The search and examination for sense and antisense is burdensome because the searches are not coextensive.

Group 2 is drawn to distinctly named modifications of the transgenic animal's genome (claim 26) and one must be elected. The modifications are insertion of a nucleic acid, inactivation of an endogenous CatSper4 gene, and insertion by homologous recombination of a reporter gene. Each modification is distinct from each

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other because each results in a different type of animal. The search and examination for each type of animal is burdensome because the searches are not coextensive.

Should "insertion of a nucleic acid" be elected in Group 2, the type of nucleic acid encoding CatSper4 or part of CatSper4, as listed in claim 27 must be elected. Each nucleic acid is distinct from each other because each encodes a protein that has different and distinct activities from each other. The search and examination for each protein is burdensome because the searches are not coextensive.

Group 3 is drawn to distinctly named proteins, SEQ ID NO. 2 and SEQ ID NO. 4, and one must be elected. Each protein is distinct from each other because each has a distinct structure and biological activity. The search and examination for each protein is burdensome because the searches are not coextensive.

Group 4 is drawn to distinctly named proteins, SEQ ID NO. 2 and SEQ ID NO. 4, to which antibodies are made, and one must be elected. SEQ ID NOs. 2 and 4 are distinct from each other because each comprises a different structure and biological activity. The search and examination for each protein is burdensome because the searches are not coextensive.

Group 5 is drawn to distinctly named indicators which are measured during the identification of a modulator (claims 42-45, 47, 48) and one must be elected. Each of the indicators is distinct from each other because each requires different method steps that detect the biological changes following administration of a candidate modulator. The search and examination for each indicator is burdensome because the searches are not coextensive.

Group 5 is drawn to distinctly named types of animals (claims 58, 60, 69, 71) to which the method of decreasing fertility is applied and one must be elected. Each of the animals has a different anatomy and different ways that fertilization occurs. The search and examination for each animal is burdensome because the searches are not coextensive.

Groups 1, 4, 5 are drawn to methods of decreasing fertility in male and female subjects and either "male" or "female" must be elected. "Male" and "female" are distinct from each other because the treatment of males and females requires distinct steps which are different from each other. The search and examination for "male" and "female" are burdensome because the searches are not coextensive.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Following the election of a SEQ ID NO. and "sense" or "antisense" of Group 1, Applicant must elect one distinct specie of a fragment of the elected SEQ ID NO. (claims 1, 2), one distinct nucleic acid that encodes portions of the elected SEQ ID NO. (claim 4), or one domain of the CatSper4 protein (claims 3 and 5). Each of the fragments or portions of CatSper4 is distinct from each other because each is structurally and functionally different from each other. The search and examination of each fragment and portion of CatSper4 are burdensome because the searches are not coextensive.

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Following the election of a SEQ ID NO. of Group 3, applicant must elect one distinct specie of a fragment of CatSper4 (claims 29, 31), one distinct protein that comprises portions of the elected SEQ ID NO. (claim 30). Each of the proteins or parts of protein is distinct from each other because each comprises a different structure and biological activity. the search and examination for each protein or part of protein is burdensome because the searches are not coextensive.

Group 5 is drawn to distinctly named domains of CatSper protein (claim 49) which are tested with a candidate compound and one must be elected. Each of the domains is different from each other because each has a different structure and biological function. The search and examination for each domain is burdensome because the searches are not coextensive.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claim(s) are generic:

Claims 1-25, 50-56, 58-67, 69-74 of Group 1 are generic for the nucleic acid sequences that encode fragments, portions, and domains of CatSper4 protein.

Claims 29-32 of Group 3 are generic for the domains and portions of CatSper4 protein.

Claims 41-55, 58-66, 69-72, 74 of Group 5 are generic for the domains of CatSper4 protein which are used to screen for compounds that modulate CatSper4 activity.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joanne Hama, Ph.D. whose telephone number is 571-272-2911. The examiner can normally be reached Monday through Thursday and alternate Fridays from 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras, can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within

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5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Joanne Hama

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